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Norman H. Stepno  
Burns, Doane, Swecker & Mathis, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

#16

In re  
Centre International de Recherches Dermatologiques  
U.S. Patent No. 5,212,30  
DIFFERIN GEL and DIFFERIN SOLUTION

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DISMISSAL OF PATENT  
TERM EXTENSION  
APPLICATIONS

Applications for patent term extension of U.S. Patent No. 5,212,30 based upon the human drug products DIFFERIN GEL and DIFFERIN SOLUTION were filed by Centre International de Recherches Dermatologiques in the Patent and Trademark Office on July 26, 1996. On July 26, 1996, applications for patent term extension of Re. 34,440, 4,717,720, and 5,015,758 were also filed based upon the regulatory review of the products DIFFERIN Gel (adapalene) and DIFFERIN Solution (adapalene).

On February 24, 1999, the PTO mailed a Notice of Final Determination in the above-noted applications informing applicant that the patent qualifies for patent term extension but for the fact that only one patent may be extended for the same regulatory review period for a product and that the patent may only receive one extension under 35 U.S.C. § 156. See 35 U.S.C. § 156(c)(4). Applicant was given a period of one-month to elect the patent for which term extension was desired for each regulatory review period.

On March 14, 1999, applicant filed a paper electing to have the term of U.S. Patent No. 4,717,720 extended based upon the regulatory review period of DIFFERIN SOLUTION and a second paper electing to have the term of U.S. Patent No. Re. 34,440 extended based upon the regulatory review period of DIFFERIN GEL. Accordingly, the applications for patent term extension of the term of U.S. Patent No. 5,212,30 based upon the regulatory reviews of DIFFERIN GEL and DIFFERIN SOLUTION are dismissed under 35 U.S.C. 156(c)(4).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson, Senior Legal Advisor  
Special Program Law Office, Office of the DAC for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: DIFFERIN GEL  
FDA Docket No.: 96E-0355

RE: DIFFERIN SOLUTION  
FDA Docket No.: 96E-0353